Ridge Augmentation Using Customized Allogenic Bone Blocks: Proof of Concept and Histological Findings

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Los of alveolar bone volume, both horizontally and vertically, is an inevitable outcome after tooth extraction.1 Resorption occurs primarily on the buccal aspect and increases over time.2 If an appropriate placement and hard tissue augmentation is performed. Besides an increase in bone volume, the rehabilitation of the contour of the alveolar process also plays an important role, especially in the aesthetic zone.

Different techniques have been developed to allow for reconstruction of the deficient ridge. The use of particulate bone grafting material allows easy contouring but requires a membrane to stabilize the graft and to avoid the ingrowth of undesired soft tissue cells.3 Titanium meshes, titanium reinforced polytetrafluoroethylene (ePTFE) membranes, and membranes made of ePTFE, titanium, collagen, or polylactide alone have been introduced. The use of particulate grafting material together with nonresorbable membranes is technically demanding, and stability as a prerequisite for rapid incorporation is difficult to achieve.4 Moreover, nonresorbable membranes have to be removed before implant placement. On the other hand, resorbable materials are lacking of adequate stability, particularly for vertical augmentations.5

In contrast to particulated materials, block grafts have the advantage of easy and stable fixation using osteosynthesis screws.6 Using a lag screw technique, they might also provide a press-fit immobilization. In combination with autogenous bone blocks, the use of an additional barrier membrane is discussed controversially in literature. Some authors concluded that a membrane is not necessary and may even delay block incorporation.7,8 Others found comparable bone volume after application of membranes.9 Nevertheless, if particulated material is used to fill voids between block and recipient site, application of membranes helps to keep the granules in place.10 Moreover, after covering the site with collagen membranes, the collagen matrix supports secondary soft tissue closure in case of dehiscence and exposure of the graft to the oral environment.5 Particularly for vertical alveolar onlay grafting, dehiscences were found to occur in up to 50% of the cases.11

Block grafts have gained popularity in recent years. For large augmentation of alveolar onlay grafts, dehiscences were found to occur in up to 50% of the cases.12

Aim: To evaluate handling and healing patterns of customized allogenic bone blocks for vertical and horizontal alveolar defect augmentation.

Materials and Methods: In 2 patients, 3 combined horizontal and vertical post-foraminal mandibular defects were grafted using computer-aided design (CAD) trimmed individual block grafts, 3D-designed on preoperative computed tomography scans. After a healing period of 6 months, graft resorption was measured and bone trephines were taken in progress of implant bed preparation. Four months later, implants were restored with single crowns. Moreover, clinical and radiological implant parameters were assessed 6 and 12 months after restorative rehabilitation.

Results: Uneventful healing was observed in 2 of the 3 cases. A partial exposure of 1 block after 8 weeks could be successfully treated by block reduction and application of a soft tissue graft. Histological evaluation revealed predictable bone formation within all augmented areas, and both patient satisfaction and long-term stability parameters were considered excellent.

Conclusions: It was concluded that the application of individual CAD allografts supports bone formation at deficient sites with reduced patient morbidity, decreased surgery time, and high patient acceptance. (Implant Dent 2013;0:1–7)

Key Words: alloblock, customized graft, augmentation, bone substitute, CAD

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volumes, the patient’s ilium is the predomi-
nating donor site. 13–15 For smaller augmen-
tation volumes, intraoral autogenous block grafts offer the ad-

vantages of reduced operating time, reduced morbidity, avoidance of hospi-

talization, and unsightly scars. 16,17 From the 2 most commonly used sites, 

the symphysis offers easier access than the ramus and higher volume but is 

associated with a higher complication rate. 18 A recent prospective study ana-

lyzing the morbidity of chin grafts found much higher rates of complica-

tions than previously reported. 19 The authors therefore strongly recommend 

not using chin grafts as donor site of first choice. 19

As an alternative to autografts, dif-

erent allograft materials have been de-

veloped. They have shown predictable results in different grafting indica-

tions in general medicine and dentistry. 20–24 The preparation process of the 

different manufacturers are considered valid with regards to the inactivation of 

viruses, bacteria, and their sterilization. 25–28 In contrast to demineralized 

dry–dried bone allografts and deproteinized xenogenic bone blocks, partly deproteinized 

bone allografts show better graft stability and can be easily fixed using osteosyn-

thesis screws. 7

In a small case series of 5 alveolar defects in 3 patients, a freeze-dried allo-

genic cancellous onlay block has been used with satisfactory results. 20 Recently, 

a larger case series of 82 blocks in 73 patients using cortico-cancellous, 

solvent-dehydrated allogenic bone blocks showed predictable bone regeneration at 

alveolar defect sites. 7 However, blocks that had not been perfectly adapted to 

the contour of the defect showed some resorption at the interface between the 

block and recipient site. Despite the avoidance of donor site complications of 

autogenous block harvesting, the necessity of meticulous shaping of the 

block did not contribute to a significant reduction of the overall surgical time.

Moreover, stereolithographic models 

are considered to be aseptic but not sterile, and the storage of the prede-

signed blocks until surgery is not clar-

ified. At last, because these blocks come with a width of maximum 1.5 

cm, several alloblocks are needed for larger augmentation areas what ham-

pers the preparation further. 30 In the 

age of 3D implantology, computerized planning and computer-aided design 

(CAD) processing might be useful tools to both perfect the graft adaption 

to the recipient site and decrease the overall surgeon’s and/or operation 

time.

In the present proof of concept study, a new allograft augmentation technique will be introduced, using customized allogene bone blocks (CABB) individually shaped for the recipient site using a preoperative dental computed tomography (CT) and a CAD-CAM technique. Particularly for extended onlay graft procedures, it might be a useful tool to avoid the donor site morbidity of autografts and decrease the time of surgery and patients’ treatment discomfort.

**Materials and Methods**

The study was performed after the STROBE Statement (Strengthening the Reporting of Observational studies in Epidemiology; www.strobe-statement.org), based on specific checklists for enforcement of cohort, case-control, and cross-sectional observational studies. To maintain a high quality of the present case report, study design, data acquisition, interpretation, and manuscript preparation was performed following the checklist for cohort studies.

**Patient Selection**

Each subject enrolled to this proof of concept study had at least 1 horizontal and vertical bone defect of the mandible in a size that required multiple intraoral donor sites or extraoral bone harvesting. Because the patients rejected this kind of surgery, the implantation of an individually pre-shaped human bone block allograft was offered.

Two systemic healthy female pa-

tients (case 1: 55 years, case 2: 45 years), 

nonsmokers for at least 6 months and not pregnant, were enrolled in the study.

After initial examination, the patients were instructed in oral hygiene and a professional tooth cleaning was performed. Plaque and bleeding scores had to be ≤15% before any surgery was done.

**Allogenic Bone Graft Material**

Human cancellous bone derived from the head of the tibia was used as block material. It was processed following the Tutoplast-protocol (Tutogen Medical GmbH, Neunkirchen am Brandt, Germany). This proprietary process uses several physicochemical steps to remove cells and antigenicity, inactivate all kinds of pathogens that may be still present besides careful donor selection and testing. Furthermore, it dehydrates the bone for convenient storage at room temperature and uses final low-dose gamma irradiation for sterilization.

**Planning and Manufacturing of the Blocks**

CT scans were performed of both patients wearing a waxed-up radiopaque scan prosthesis to evaluate the ideal position of the implants. Data was transferred to a 3D planning software (SimPlant; Materialise Dental NV, Leuven, Belgium). Taking into account clinical and aesthetic considerations, ideal implant positions and respective defect morphology were defined (Fig. 1). Using a special software tool, the missing bone area could then be drawn directly on the 3D surface of the deficient ridge. These data, providing a 3D information about the morphology of the bone graft, were converted in a *.stl file and sent to the company (Materialize, Leuven, Belgium). There, CNC programming was done and the graft was milled out of a single block of bone allograft (Fig. 2). After cleaning, packaging, and sterilization, the individual bone block was sent back to the surgeon.

**Surgical Technique**

Bone blocks were retained sterile from the double blister package and rehydrated with sterile 0.9% saline solution. To maintain complete rehy-

dration even in the center of the blocks, the rehydration was performed in a ster-

ile syringe, retracting the plunger every
few minutes for at least 30 minutes until no more air bubbles came out of the block graft (Fig. 3).

Surgeries were done under infiltration with local anesthesia (Ultracain-DS forte; Aventis Pharma, Frankfurt, Germany). A midcrestal incision was made at the recipient site and extended intrasulcularly to the neighboring teeth. Releasing incisions were performed interdentally (Fig. 4). On the buccal side, a full-thickness flap was raised to the mucogingival junction. After separating the periosteum, the preparation of the flap was continued with a split thickness technique. Lingually, a full-thickness flap was prepared and the periosteum was separated at the base, allowing for mobilization of the flaps and tense-free soft tissue closure over the graft. Residual soft tissue was removed to get access to the bone. The cortical bone at the recipient site was perforated with a fissure bur to support blood vessel outgrowth. The pre-shaped and rehydrated bone block was applied and fixed using 4 osteosynthesis screws (Mondeal; PSM Medical Solutions, Tuttlingen, Germany).

The heads of the screws were countersunk even to the block surface as reference point for resorption measurement (Fig. 5). To get a smoother transition of the round edges of the blocks maintaining a minimal thickness of the material, particulated allograft material (Navigraft; Tutogen) was applied in the peripheral areas. Grafted areas were covered with a collagen membrane (Bio-Gide; Geistlich, Wohlhusen, Switzerland). The flaps were repositioned and sutured passively with a combination of mattress and running polypropylene 6-0 sutures (Premilene; Braun Melsungen, Melsungen, Germany).

### Table 1. Soft Tissue Thickness, Surgery Time, Screw Number, Postoperative Pain and Presence of Wound Healing Complications at CABB-Grafted Sites

<table>
<thead>
<tr>
<th>Area</th>
<th>Soft Tissue Thickness, mm</th>
<th>Surgery Time, min</th>
<th>No. of Screws</th>
<th>Pain 1 d postoperative (VAS)</th>
<th>Wound-Healing Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1 right mandible</td>
<td>45, 46, 47</td>
<td>0.5</td>
<td>46</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>P1 left mandible</td>
<td>35, 36, 37</td>
<td>0.6</td>
<td>35</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>P2 right mandible</td>
<td>45, 46, 47</td>
<td>0.8</td>
<td>42</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

VAS indicates visual analog scale.
Post surgical Protocol

A conventional x-ray was performed after the surgery (Fig. 6). Patients were instructed to avoid any mechanical trauma of the wound. Mechanical alteration and tooth brushing in the treated area was not allowed for 4 weeks. Plaque control was achieved by mouth rinsing with chlorhexidine solution (0.12% Butler Paroex; Sunstar, Chicago, IL) twice a day for 1 minute. Ibuprofen (Ibumerck; Merck AG, Darmstadt, Germany) as a nonsteroid and anti-inflammatory analgesic was prescribed. Augmentin tablets 875/125 mg (GlaxoSmithKline, Brentford, Middlesex, GB) was prescribed for 7 days. Sutures were removed 2 weeks after surgery. Wounds were controlled every 4 weeks.

Implant Insertion and Reevaluation

After 6 months, sites were reopened and block resorption was assessed by measuring the distance of the head of the osteosynthesis screw to the surface of the regenerated bone using a periodontal probe. A biopsy was taken in progress of implant bed preparation at 6 implant sites by replacing the first implant bur with a trephine (inner diameter: 2 mm; Stoma, Tuttingen, Germany).

Six Camlog and 3 Astra implants were installed according to the manufacturer’s protocols. Hereby, platform of Camlog implants were positioned 2

Table 2. Radiological Bone Resorption at Implants and Clinical Parameters 6 and 12 months After Prosthetic Restoration

<table>
<thead>
<tr>
<th>Patient and Area</th>
<th>Implant Position</th>
<th>6 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RD</td>
<td>RM</td>
<td>SUP</td>
</tr>
<tr>
<td>P1 right mandible</td>
<td>45</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>46</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>P1 left mandible</td>
<td>35</td>
<td>0.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>1.5</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>P2 right mandible</td>
<td>45</td>
<td>0</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>46</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>47</td>
<td>3.5</td>
<td>3.5</td>
</tr>
</tbody>
</table>

RD indicates distal resorption, RM, mesial resorption.
mm supracrestally and Astra implants even. At implant uncovering 4 months later, a free gingival graft was positioned on the buccal side of the healing abutments to thicken the soft tissue and improve keratinized gingiva around the implants. Restorative procedures started after soft tissue maturation. At 6 and 12 months after restorative rehabilitation with single crowns, the radiological position of interproximal bone level as the distance between platform and crestal bone, plaque index (PI), gingival index (GI), and suppuration (SUP) were assessed.

**Histological Processing and Evaluation**

The trephines were fixed in 4% neutral buffered formalin solution for at least 3 days. Samples were decalcified using EDTA and embedded in paraffin. Serial sections of 7-μm thickness were stained with hematoxylin/eosin. For image acquisition, a digital camera (Nikon D100; Nikon GmbH, Duesseldorf, Germany) was mounted on a binocular light microscope (Olympus BX50; Olympus, Hamburg, Germany).

**RESULTS**

During the grafting procedure, individual bone blocks fitted exactly to the recipient sites. No further grinding or adapting was necessary (Fig. 5). Total surgery time was assessed 41 ± 4.5 minutes on average. Soft tissue thickness was measured between 5 and 8 mm (Table 1).

Initial wound healing was uneventful in all cases. Postoperatively, no infection or clinical signs of inflammation could be observed. However, 2 months after surgery, a partial exposure of 6 × 10 mm of 1 bone block was observed. In this case, a full-thickness flap was raised and the superficial 1 mm of the exposed bone was removed using a round diamond bur until it started to bleed out of the bone matrix. A connective tissue graft from the palate (10 × 20 mm) was placed on top of the bone graft, and the flap was closed over the site. Antibiotics and analgesics as aforementioned were prescribed again, and sutures were removed after 2 weeks.

After 6 months healing time, all augmented sites revealed inflammation-free soft tissue conditions. Grafted areas showed revitalization and slight bleeding out of the bone matrix after mucoperiosteal flap elevation. In line with the other sites, the formerly exposed area was without any sign of inflammation at the time of implant placement. All planned implants could be installed (Fig. 7).

**Graft Resorption and Clinical Measurements**

Volume loss of the grafts evaluated at the osteosynthesis screws in progress of implant installation showed an average height loss of 2 mm in the case that showed the wound-healing complication, whereas the other 2 grafted areas revealed no resorption. Crestal bone loss at implants 6 and 12 months after prosthetic rehabilitation are shown in Table 2. An average bone loss of 1.69 ± 3.31 mm (1.64 + 1.22 mm) was observed 6 (12) months after installment of the implants (Table 2). Clinical parameters GI, PI, and SUP showed stable conditions after 6 and 12 months (Table 2).

**Histological Evaluation**

The histology of all 6 trephines showed complete bony regeneration of the augmentation material (Figs. 8 and 9). In some areas, the bone substitute matrix could still be distinguished in some areas due to their slightly different staining behavior and empty osteocytes lacunae. The majority of the individual bone substitute remnants were surrounded by the newly formed bone (Fig. 10). Normal bone marrow was visible between the bone trabeculae. Absorption of the material was observed regularly, directly connected with new bone apposition.

**DISCUSSION**

In the present case report, augmentation of 3 extended alveolar defects using customized allogeneous bone blocks (CABB) was evaluated. It was found that due to their good adaption to the recipient site, blocks were fast and easy to apply, reducing the surgery time and patients’ discomfort. Despite a delayed partial exposure of one block with subsequent loss of the superficial part, osseous organization of the grafts occurred in all cases.

Extensive augmentations of the severely compromised alveolar process require high surgical skills and experience and are very often treated with autogenous blocks from intraoral or extraoral donor sites. The use of allogeneous bone blocks may avoid donor site morbidity, reducing the risk of complications and perioperative discomfort for the patient. In some cases, even general anesthesia and extraoral bone harvesting may not be required anymore because alloblocks are not limited in availability.

The allograft material used for the production of CABB is well established for many years for dental and orthopedic applications. Particles of this material have been shown to be nearly completely absorbed and replaced by new vital bone in the maxillary sinus within 8 to 10 months. The newly formed bone has the same quality and density as the patient’s residual bone. It was successfully used in periodontal defects and furcation defects. Implants placed in extraction sockets 4 to 7 months after grafting with this material had a 3-year survival rate of 97.6%. Even huge defects after tumor resection exceeding 100 cm³ could be successfully reconstructed with this material. In a prospective randomized trial investigating healing outcome of grafted radius fractures, it was found that this material offers the same results as autogenous bone.

If a material is not used in granule form but in block shape, the stabilization and intimate contact of the block surface to the recipient bed has been considered crucial for a successful outcome. However, trimming and adaptation of a standard alloblock requires additional surgery time. The blocks have to be placed several times on the defect for checking the fit and have to be removed again to be trimmed. This process induces a high risk for contamination in the mouth by saliva or extrorally by the surgeon. Moreover, particularly in nonexperienced hands,
the preparation of a blood-loaded block might be accompanied by an infection risk for the surgeon or a total loss of the graft caused by inadequate use of the preparation burs and falling down in a nonsterile area.

Because individually preformed blocks do not need to be trimmed chair-side, they fit perfectly without the necessity of any chair-side adaptation. Surgical time and thus surgical costs are reduced drastically. In contrast to blocks adapted during previous surgery by the surgeon on a stereolithographic model, industrially produced CABBs do not require the surgeon’s practical experience and time before performing the actual surgery. Moreover, from the hygienic point of view, CABBs remain absolutely sterile until the actual surgical procedure.

In terms of treatment costs, both stereolithographic models and CAD individualization are extending the expenses, which can be compensated by reduced surgery time. However, a part of that compensation will be consumed by increased material costs. Compared with autogenous bone blocks, especially harvested from extraoral donor sites, the overall costs of the treatment might be considered much lower. Furthermore, the surgical procedure of application of CABB might be easier to perform than trimming and adaptation of autogenous bone blocks.

Although the graft fixation seems to be facilitated using CABB, the soft tissue management still stays crucial. A tensionless flap design is still mandatory to keep the flap closed during healing time.11 In one of the cases, a late exposition of the block occurred. As expected, early vascularization seems to be a similar risk for both CABB and conventional techniques.

Graft resorption during the initial healing period may be the result of the initial remodeling of the graft. In contrast to xenogenous bone grafts such as BioOss, remodeling of collagen-rich allogenous bone is considered fast, which might be accompanied with superficial volume loss.42 However, complete deproteinization as applied in xenogenous materials leads to fragile block properties. This impedes the ability of screw fixation and decreases the speed of osseous remodeling.43 In the present study, only in 1 site an advanced resorption of the block grafts was observed, as a result of a late dehiscence and necessity of block graft reduction.

Crestal bone resorption after implant installation is owed to the remodeling around the implant or further remodeling of CABB. It was shown that also implants placed in preexisting bone show crestal bone loss. Several theories have been stated about this phenomenon, starting from microleakage at the implant-abutment connection to inflammatory effects based on sealing material to inadequate loading.44 In this context, it has to be pointed out that although a crestal bone loss occurred, no implant was lost during the initial observing period. One implant showed higher clinical parameters. However, a relation to the CABB grafting is doubtful due to the health of the neighboring implants. Clinically controlled studies with larger patient numbers will be necessary to specifically assess the differences between CABB, conventional allogenic bone block augmentation, and autogenous block grafts.

CONCLUSIONS AND CLINICAL RELEVANCE

Use of customized allogenous bone blocks supports bone formation and reduces surgery time, the risk of contamination of the graft, and the patient morbidity. Although soft tissue management still remains crucial, it might be a useful tool for easy and patient-friendly treatment of extended alveolar bone defects.

DISCLOSURE

Dr Schlee states that he has “financial interest in 3D-Blocks provided by Botiss Biomaterials, Berlin, Germany”. Dr Rothamel claims to be a consultant for, and receives payments for lectures, from Botiss Biomaterials, Berlin, Germany. The other authors do not have any financial interests in any of the products mentioned in this article.

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